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AF/1617

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	)	
	)	
ANDREW J. DANNENBERG.	)	Group Art Unit: 1617
	)	
Patent Application No. 09/554,604	)	Examiner: S. Wang
	)	
Filed: May 31, 2000	)	
	)	
For: CYCLOOXYGENASE-2 INHIBITION	)	

REPLY TO SUPPLEMENTAL EXAMINER'S ANSWER
PURSUANT TO 37 C.F.R. 1.193 (b)(1)
(In Triplicate)

Honorable Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is in reply to the Supplemental Examiner's Answer of December 11, 2003.

Please consider the following:

On August 20, 2003, the undersigned submitted a copy of Yamamoto, H., et al., Gastroenterology 125, 556-571 (2003) as evidence of no expectation of success to one skilled in the art from the cited art combination.

The Supplemental Examiner's Answer takes two positions in response.

Firstly, the Supplemental Examiner's Answer takes the position that Yamamoto is too late to be evidence of expectation of success because it published five years after the effective filing date. In response, the undersigned contends that the later publication date is the most relevant date. Yamamoto shows that even in 2003 there is not expectation of success. **It is submitted that if there is no expectation of success even in 2003, there should not have been an expectation of success earlier.** An article published before the invention would be subject to

the criticism that there may have been a reasonable expectation of success after publication and before invention. Under the scenario posed by the Examiner's supplemental answer, the only pertinent evidence would be a publication at the date of invention. It is submitted that this would be an unreasonable standard.

Secondly, the Supplemental Examiner's Answer takes the position that the test of Yamamoto was to confirm a reasonable expectation. A reading of Yamamoto indicates confirmation was not the purpose of the test, but rather to establish whether selective inhibitors of COX-2 would prevent cirrhosis. Consider the following language in the first paragraph under "Discussion" in Yamamoto et al.

> Previous studies showed that the nonselective COX inhibitors piroxicam and acetylsalicylic acid prevented cirrhosis and development of preneoplastic nodules in CDAA-treated rats. 18,33 One of the aims of our study was to examine whether selective inhibition of COX-2 alone would be sufficient to realize this goal because such inhibition appears to yield much less toxicity than other nonsteroidal anti-flammatory drugs.

In other words, testing was necessary to exclude the need of significant COX-1 inhibition to obtain cirrhosis preventing effect.

Reversal of the rejection is requested.

Respectfully submitted,

JONES, TULLAR & COOPER, P.C.

By: 

Eric S. Spector
Reg. No. 22,495

JONES, TULLAR & COOPER, P.C.
P.O. Box 2266 Eads Station
Arlington, Virginia 22202
703-415-1500

Case: CRF D-2165

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